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## FACSIMILE TRANSMITTAL

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Gary K. Michelson
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THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS
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**TRANSMISSION 4(C) OF 4**

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I hereby certify that the attached Transmittal Form (in duplicate; $1,020.00 total amount to cover the three-month extension fee is to be charged to Deposit Account No. 50-1068), Reply to Office Action, Declaration of Gary K. Michelson Under 37 C.F.R. § 1.131 with Exhibits A and B, and Declaration of Amedeo F. Ferraro with Exhibits A-H are being facsimile transmitted to the U.S. Patent and Trademark Office on September 30, 2005.

Todd M. Martin

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substantially uniform radius $R_6$ measured from the central longitudinal axis $L_6$ of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis $L_6$. It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis $L_6$, such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from the body 522 that increases from the insertion end 524 to the trailing end 526.

Referring to Figure 13, a segment of the spinal column S is shown with the vertebrae $V_1$ and $V_2$ in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to in initially distract apart the vertebrae $V_1$ and $V_2$ which then angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae $V_1$ and $V_2$ to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae $V_1$ and $V_2$.

In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius $R_6$ in the range of 6 mm to 12 mm, with 8 mm being the preferred radius $R_6$.

Referring to Figure 14, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second

identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis $L_1$. In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius $R_6$ measured from the central longitudinal axis $L_1$ that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius $R_1$ that is variable with respect to the longitudinal axis $L_1$ such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

Referring to Figure 15, an end view of the implant 620 placed beside implant 621 is shown. The implant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread 628 at the side 670 or 672 of the implants.

Referring to Figure 16, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a

root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

The outer surface of the body 722 of implant 720 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances. If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

~~The embodiments of the frusto-conical implants of the~~ present invention described above may be implanted with the method described below.

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis have been achieved at the affected disc level, then a frusto-conical space is created from anterior to posterior between the adjacent vertebrae. The frusto-conical space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae. The created space is generally frusto-conical in shape, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepare two such frusto-conical spaces

side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the frusto-conical space is prepared and all debris removed, the implant is then inserted into the prepared space across the disc space, penetrating into each of the adjacent vertebrae, from anterior to posterior.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. 08/396,414 entitled Apparatus and Method of Inserting Spinal Implants, incorporated herein by reference, is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the spine. As previously described in U.S. Patent Application Serial No. 08/396,414, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. 08/396,414, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described interspace distractor. However, if the interspace distractor is used, then the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

Referring to Figure 17, a segment of the spinal column S is shown with vertebrae $V_1$ and $V_2$ shown in lordosis adjacent to disc space $D_1$ and vertebrae $V_2$ and $V_3$ shown not in lordosis, but relatively parallel to each other adjacent disc space $D_2$. A first

drill 810 making an opening 812 across the disc space $D_1$, and into adjacent vertebrae $V_1$ and $V_2$, and a second drill 820 making an opening 822 across the disc space $D_2$ and into adjacent vertebrae $V_2$ and $V_3$ are shown in Figure 17. In the preferred embodiment, the interbody spinal fusion implant itself is threaded and frusto-conical in shape and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention, by way of example. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root dimensions of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion of the first drill 510 generally corresponding to the frusto-conical shape of the root diameter of the implant being inserted. This instrument may take the form of a frusto-conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with power. Having prepared the space, the surgeon has two options. One is to remove the outer sleeve and then, because the implant is itself frusto-conical, screw the implant in using an implant driver capable of locking to the implant. The other is to leave the outer sleeve in place during the insertion of the implant.

If per the above, the surgeon wishes to remove the outer sleeve, the insertion of the implant itself causes a reproduction of the previous distraction which is easily achieved as the implant itself is frusto-conical in shape and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the implant is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from the implant. If the

cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same disc level, such that a pair of implants may be inserted side-by-side.

In the alternative, if the surgeon wishes to leave the outer sleeve in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the bone removing portion of the drilling means needs to generally correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be great enough to allow the passage of the major diameter of the implant. It is desirable to stabilize the bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. This may be achieved by a reduction sleeve which fits between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant, or some portion of the drill shaft proximal to the cutting end may have a diameter which corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In either way, the bone removal instrument is both stabilized and centered within the outer sleeve.

The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No. 08/396,414

[REDACTED] As also previously described, in co-

pending application Serial No. 08/396,414, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application 08/390,131, the implants themselves may have truncations on the sides to form a planar surface parallel to the longitudinal axis of the implant, such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height.

Referring again to Figure 17, in an alternative method of implant insertion, the use of at least partially frusto-conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is present to begin with as with the angular relationship of $V_2$ and $V_3$ shown in Figure 17. As per this example, the disc space $D_2$ which in the preferred circumstance would be fully distracted but need not be, but lacking lordosis, could have a bore drilled across that space such that equal arcs of bone $A_1$ and $A_2$ are removed from each of the adjacent vertebrae $V_2$ and $V_3$ using a drill 820 or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The essential feature here is that the vertebrae $V_2$ and $V_3$, whether distracted from each other or not, are essentially lacking the full restoration of lordosis. The use of the substantially cylindrical bone drill 820 provides for the removal of a generally uniform thickness of bone from each of the adjacent vertebrae from anterior to posterior. The insertion of a frusto-conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart more so than the posterior aspects where the diameter is lesser. This utilizes the implant to produce the desired lordosis.

The method for the insertion of the spinal fusion implants of the present invention from the posterior aspect of the spine is described in detail in co-pending patent Application Serial No. 08/396,414 and is incorporated herein by reference. Further, in the method of inserting the implants of the present invention from the posterior aspect of the spine, it is possible to place the adjacent vertebrae in lordosis prior to the bone removal step.

Referring to Figures 18 and 19, spinal distractor 900 is shown which is used for distracting the adjacent vertebrae in lordosis prior to the bone removal step. The spinal distractor 900 has a tapered insertion end 902 to facilitate insertion, an instrument engaging end 904, and top and bottom surfaces 906 and 908. The top and bottom surfaces 906 and 908 are in a angular relationship to each other and are furthest apart at a point near the insertion end 902 to produce the desired lordosis when inserted in the disc space between two adjacent vertebrae. The top and bottom surfaces 906 and 908 have surface roughenings 910 for engaging the bone of the adjacent vertebrae and stabilizing the spinal distractor 900 when inserted.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

What is claimed is:

1. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an outer surface; and

~~bone engaging means~~ AN EXTERNAL THREAD for engaging said implant to adjacent vertebrae of the spine, the outer locus of said ~~bone engaging means~~ EXTERNAL THREAD forming a substantially frusto-conical configuration, said implant being made of a material appropriate for human implantation.

2. The implant of claim 1 in which said body has a substantially frusto-conical configuration.

3. The implant of claim 1 in which said body has a substantially cylindrical configuration.

4. The spinal fusion implant of claim 1 in which said trailing end is larger than said insertion end.

5. The spinal fusion implant of claim 1 in which said insertion end is larger than said trailing end.

6. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

7. The spinal fusion implant of claim 1 in which said implant comprises a fusion promoting material.

8. The spinal fusion implant of claim 1 in which said implant is at least in part bioabsorbable.

9. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

10. The spinal fusion implant of claim 1 in which said bone engaging means comprises an external thread.

11. The spinal fusion implant of claim ~~10~~ 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout at least a portion of said implant.

12. The spinal fusion implant of claim ~~10~~ 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along the length of said implant.

13. The spinal fusion implant of claim ~~10~~ 1 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

14. The spinal fusion implant of claim ~~10~~ 1 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

15. The spinal fusion implant of claim 1 in which said ~~bone engaging means comprises said~~ outer surface ~~being~~ is porous at least in part.

~~16.~~ The spinal fusion implant of claim 1 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

17. The spinal fusion implant of claim 16 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

18. The spinal fusion implant of claim 1 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

~~19. The spinal fusion implant of claim 1 in which said bone~~

engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

20. The spinal fusion implant of claim 19 in which said surface roughenings include a plurality of ratchetings.

21. The spinal fusion implant of claim 19 in which said surface roughenings include knurling.

22. The spinal fusion implant of claim 1 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

23. The spinal fusion implant of claim 22 in which said internal chamber is capable of containing fusion promoting material.

24. The spinal fusion implant of claim 22 in which said implant comprises a wall surrounding said internal chamber.

25. The spinal fusion implant of claim 22 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

26. The spinal fusion implant of claim 22 in which said implant has means for closing said access opening.

27. The spinal fusion implant of claim 1 in which said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

28. The spinal fusion implant of claim 1 in which at least a portion of said outer surface comprises wells having at least partial walls.

29. The spinal fusion implant of claim 1 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

30. The spinal fusion implant of claim 1 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

31. The spinal fusion implant of claim 30 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

32. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an outer surface; and

~~bone engaging means~~ AN EXTERNAL THREAD for engaging said implant to adjacent vertebrae of the spine, the locus of said ~~bone engaging means~~ EXTERNAL THREAD forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

33. The implant of claim 32 in which said body has a substantially frusto-conical configuration.

34. The implant of claim 32 in which said body has at least in part a cylindrical configuration.

35. The spinal fusion implant of claim 32 in which said trailing end is larger than said insertion end.

36. The spinal fusion implant of claim 32 in which said insertion end is larger than said trailing end.

37. The spinal fusion implant of claim 32 in which said implant comprises a bone ingrowth material.

38. The spinal fusion implant of claim 32 in which said implant comprises a fusion promoting material.

39. The spinal fusion implant of claim 32 in which said implant is at least in part bioabsorbable.

40. The spinal fusion implant of claim 32 having a plurality of openings capable retaining fusion promoting material.

41. The spinal fusion implant of claim 32 in which said bone engaging means comprises an external thread.

42. The spinal fusion implant of claim ~~41~~ 32 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout the length of said implant.

43. The spinal fusion implant of claim ~~41~~ 32 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along at least a portion of said implant.

44. The spinal fusion implant of claim ~~41~~ 32 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

45. The spinal fusion implant of claim ~~41~~ 32 in which said external thread has a thread height measured from said body which is substantially constant along at least a portion of said implant.

46. The spinal fusion implant of claim 32 in which ~~said bone engaging means comprises~~ said outer surface ~~being~~ porous at least

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in part.

47. The spinal fusion implant of claim 32 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

48. The spinal fusion implant of claim 47 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

49. The spinal fusion implant of claim 32 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

50. The spinal fusion implant of claim 32 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

51. The spinal fusion implant of claim 50 in which said surface roughenings include a plurality of ratchetings.

52. The spinal fusion implant of claim 50 in which said surface roughenings include knurling.

53. The spinal fusion implant of claim 32 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

54. The spinal fusion implant of claim 53 in which said internal chamber is capable of containing fusion promoting material.

55. The spinal fusion implant of claim 53 in which said implant comprises a wall surrounding said internal chamber.

56. The spinal fusion implant of claim 53 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

57. The spinal fusion implant of claim 53 in which said implant has means for closing said access opening.

58. The spinal fusion implant of claim 32 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

59. The spinal fusion implant of claim 32 in which at least a portion of said outer surface comprises wells having at least partial walls.

60. The spinal fusion implant of claim 32 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

61. The spinal fusion implant of claim 32 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

62. The spinal fusion implant of claim 61 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

63. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the outer locus of said bone engaging means

forming a substantially frusto-conical configuration, said implant being made of a material appropriate for human implantation.

64. The spinal fusion implant of claim 63 in which said trailing end is larger than said insertion end.

65. The spinal fusion implant of claim 63 in which said insertion end is larger than said trailing end.

66. The spinal fusion implant of claim 63 in which said implant comprises a bone ingrowth material.

67. The spinal fusion implant of claim 63 in which said implant comprises a fusion promoting material.

68. The spinal fusion implant of claim 63 in which said implant is at least in part bioabsorbable

69. The spinal fusion implant of claim 63 having a plurality of openings capable retaining fusion promoting material.

70. The spinal fusion implant of claim 63 in which said bone engaging means comprises an external thread.

71. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout at least a portion of said implant.

72. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along the length of said implant.

73. The spinal fusion implant of claim 70 in which said external

thread has a thread height measured from said body which is variable along the length of said implant.

74. The spinal fusion implant of claim 70 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

75. The spinal fusion implant of claim 63 in which said bone engaging means comprises said outer surface being porous at least in part.

76. The spinal fusion implant of claim 63 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

77. The spinal fusion implant of claim 76 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

78. The spinal fusion implant of claim 63 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

79. The spinal fusion implant of claim 63 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

80. The spinal fusion implant of claim 79 in which said surface roughenings include a plurality of ratchetings.

81. The spinal fusion implant of claim 79 in which said surface roughenings include knurling.

82. The spinal fusion implant of claim 63 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

83. The spinal fusion implant of claim 82 in which said internal chamber is capable of containing fusion promoting material.

84. The spinal fusion implant of claim 82 in which said implant comprises a wall surrounding said internal chamber.

85. The spinal fusion implant of claim 82 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

86. The spinal fusion implant of claim 82 in which said implant has means for closing said access opening.

87. The spinal fusion implant of claim 63 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

88. The spinal fusion implant of claim 63 in which at least a portion of said outer surface comprises wells having at least partial walls.

89. The spinal fusion implant of claim 63 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

90. The spinal fusion implant of claim 63 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

91. The spinal fusion implant of claim 90 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

92. An interbody spinal fusion implant, comprising:

a body having a substantially cylindrical configuration, an insertion end, a trailing end and an outer surface; and

~~bone engaging means~~ [AN EXTERNAL THREAD] for engaging said implant to adjacent vertebrae of the spine, the locus of said [EXTERNAL THREAD] ~~bone engaging means~~ forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

93. The spinal fusion implant of claim 92 in which said implant comprises a bone ingrowth material.

94. The spinal fusion implant of claim 92 in which said implant comprises a fusion promoting material.

95. The spinal fusion implant of claim 92 in which said implant is at least in part bioabsorbable

96. The spinal fusion implant of claim 92 having a plurality of openings capable retaining fusion promoting material.

97. The spinal fusion implant of claim 93 in which said bone engaging means comprises an external thread.

98. The spinal fusion implant of claim ~~97~~ 92 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform for at least a portion of said implant..

99. The spinal fusion implant of claim ~~97~~ 92 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along at

least a portion of said implant.

100. The spinal fusion implant of claim ~~91~~ 92 in which said external thread has a thread height measured from said body which is variable along at least a portion of said implant.

101. The spinal fusion implant of claim ~~91~~ 92 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

102. The spinal fusion implant of claim 93 in which said ~~bone engaging means comprises said~~ outer surface ~~being~~ porous at least in part. L15

103. The spinal fusion implant of claim 93 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

104. The spinal fusion implant of claim 103 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

105. The spinal fusion implant of claim 93 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

106. The spinal fusion implant of claim 93 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

107. The spinal fusion implant of claim 106 in which said surface roughenings include a plurality of ratchetings.

108. The spinal fusion implant of claim 106 in which said surface roughenings include knurling.

109. The spinal fusion implant of claim 93 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

110. The spinal fusion implant of claim 109 in which said internal chamber is capable of containing fusion promoting material.

111. The spinal fusion implant of claim 109 in which said implant comprises a wall surrounding said internal chamber.

112. The spinal fusion implant of claim 109 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

113. The spinal fusion implant of claim 109 in which said implant has means for closing said access opening.

114. The spinal fusion implant of claim 93 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

115. The spinal fusion implant of claim 93 in which at least a portion of said outer surface comprises wells having at least partial walls.

116. The spinal fusion implant of claim 93 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

117. The spinal fusion implant of claim 93 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

118. The spinal fusion implant of claim 117 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

119. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

~~bone engaging means~~ AN EXTERNAL THREAD for engaging said implant to adjacent vertebrae of the spine, said implant being made of a material appropriate for human implantation.

120. The ~~implant~~ of claim 119 in which the outer locus of said bone engaging means forms a substantially ~~frusto~~-conical configuration.

121. The implant of claim 119 in which said the outer locus of said ~~bone engaging means~~ EXTERNAL THREAD forms a substantially cylindrical configuration.

122. The spinal fusion implant of claim 119 in which said insertion end is larger than said trailing end.

123. The spinal fusion implant of claim 122 in which said insertion end comprises a tapered leading portion.

124. The spinal fusion implant of claim 119 in which said trailing end is larger than said insertion end.

125. The spinal fusion implant of claim 119 in which said implant comprises a bone ingrowth material.

126. The spinal fusion implant of claim 119 in which said implant

comprises a fusion promoting material.

127. The spinal fusion implant of claim 119 in which said implant is at least in part bioabsorbable.

128. The spinal fusion implant of claim 119 having a plurality of openings capable retaining fusion promoting material.

129. The spinal fusion implant of claim 119 in which said bone engaging means comprises an external thread.

130. The spinal fusion implant of claim ~~129~~ 119 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout the length of said implant.

131. The spinal fusion implant of claim ~~129~~ 119 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along the length of said implant.

132. The spinal fusion implant of claim ~~129~~ 119 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

133. The spinal fusion implant of claim ~~129~~ 119 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

134. The spinal fusion implant of claim 119 in which said ~~bone engaging means comprises said~~ outer surface ~~being~~ porous at least in part. 15

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135. The spinal fusion implant of claim 119 in which said bone engaging means comprises a plurality of posts spaced apart along at

least a portion of the outer surface of said body.

136. The spinal fusion implant of claim 135 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

137. The spinal fusion implant of claim 119 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

138. The spinal fusion implant of claim 119 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

139. The spinal fusion implant of claim 138 in which said surface roughenings include a plurality of ratchetings.

140. The spinal fusion implant of claim 138 in which said surface roughenings include knurling.

141. The spinal fusion implant of claim 119 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

142. The spinal fusion implant of claim 141 in which said internal chamber is capable of containing fusion promoting material.

143. The spinal fusion implant of claim 141 in which said implant comprises a wall surrounding said internal chamber.

144. The spinal fusion implant of claim 141 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

145. The spinal fusion implant of claim 141 in which said implant has means for closing said access opening.

146. The spinal fusion implant of claim 119 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

147. The spinal fusion implant of claim 119 in which at least a portion of said outer surface comprises wells having at least partial walls.

148. The spinal fusion implant of claim 119 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

149. The spinal fusion implant of claim 119 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

150. The spinal fusion implant of claim 149 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

151. A method for inserting at least one frusto-conical spinal fusion implant made of a material appropriate for human implantation, said implant having bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc and placing the two vertebrae in the desired amount of lordosis;

drilling a frusto-conical recipient bore across the disc space and into the adjacent vertebrae, said bore being at least in part

greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a frusto-conical spinal fusion implant into said recipient bore.

152. The method claim 151 in which said bore is greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

153. The method claim 151 in which said bore is greatest in diameter posteriorly and tapering to a lesser diameter anteriorly.

154. The method of claim 151 in which said step of drilling includes the use of a drill having a substantially frusto-conical shaped bone removing means.

155. The method of claim 151 in which a second spinal fusion is implanted across the disc space engaging each of the adjacent vertebrae side by side and adjacent to said first spinal fusion implant.

156. The method of claim 155 comprising the step of drilling a second recipient bore across the disc space partially overlapping said first bore, the combined width of said first and second recipient bores being less than the sum of the individual diameters of said first and second recipient bores; and inserting a second spinal fusion implant.

157. The method of claim 151 in which said method is performed from the anterior aspect of the spinal column.

158. The method of claim 151 in which said method is performed from the posterior aspect of the spinal column.

159. The method of claim 151 in which the step of drilling said

recipient bore includes the removal of a portion of bone parallel to the endplates of said adjacent vertebrae.

160. A method for inserting at least one frusto-conical spinal fusion implant made of a material appropriate for human implantation, said implant having bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc;

drilling a recipient bore across the disc space and into the adjacent vertebrae, said bore being at least in part greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a frusto-conical spinal fusion implant into said recipient bore.

161. The method of claim 160 in which said recipient bore is generally cylindrical in shape.

162. The method of claim 160 in which said step of drilling includes the use of a drill having a substantially cylindrical shaped bone removing means.

163. The method of claim 160 in which a second spinal fusion is implanted across the disc space engaging each of the adjacent vertebrae side by side and adjacent to said first spinal fusion implant.

164. The method of claim 163 comprising the step of drilling a second recipient bore across he disc space partially overlapping said first bore, the combined width of said first and second recipient bores being less than the sum of the individual diameters of said first and second recipient bores; and inserting a second spinal fusion implant.

165. The method of claim 160 in which said method is performed from the anterior aspect of the spinal column.

166. The method of claim 160 in which said method is performed from the posterior aspect of the spinal column.

167. The method of claim 160 in which the step of drilling said recipient bore includes the removal of a portion of bone parallel to the endplates of said adjacent vertebrae.

168. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the outer locus of said bone engaging means forming a substantially frusto-conical configuration substantially along a portion of said bone engaging means in contact with said adjacent vertebrae, said implant being made of a material appropriate for human implantation.

169. The implant of claim 168 in which said body has a substantially frusto-conical configuration substantially along a portion of said outer surface in contact with said adjacent vertebrae.

170. The implant of claim 168 in which said body has a substantially cylindrical configuration substantially along a portion of said outer surface in contact with said adjacent vertebrae.

171. The spinal fusion implant of claim 168 in which said bone engaging means comprises an external thread.

172. The spinal fusion implant of claim 168 in which said bone engaging means comprises a plurality of posts spaced apart along at

least a portion of the outer surface of said body.

173. The spinal fusion implant of claim 168 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

174. The spinal fusion implant of claim 168 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

175. The spinal fusion implant of claim 168 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

176. A spinal fusion implant, comprising:

a body having an outer locus larger than the space between two adjacent vertebrae to be fused, said outer locus being substantially cylindrical along a portion of said implant in contact with said adjacent vertebrae; and

~~bone engaging means~~ [NEW ELEMENT THEREIN for engaging said implant to said adjacent vertebrae of the spine on the exterior of said body, said implant being made of a material appropriate for human implantation.

177. The spinal fusion implant of claim 176 including a plurality of openings in the exterior surface of said implant.

178. The spinal fusion implant of claim 176 in which said bone engaging means comprises an external thread.

179. The spinal fusion implant of claim 176 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

180. The spinal fusion implant of claim 176 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

181. The spinal fusion implant of claim 176 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

182. The spinal fusion implant of claim 176 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

## ABSTRACT

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration, ~~and the instrumentation and methods by which the implants of the present invention can be utilized to achieve a desired anatomical lordosis of the spine~~. The spinal fusion implants of the present invention may be relatively solid or hollow and ~~may~~ STED have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. ~~A variety of surface irregularities may be~~ EXTERNAL THREADS 15 employed to increase implant stability and implant surface area, and ~~of~~ for the purpose of advancing the spinal fusion implant into the fusion site.

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**EXHIBIT G**

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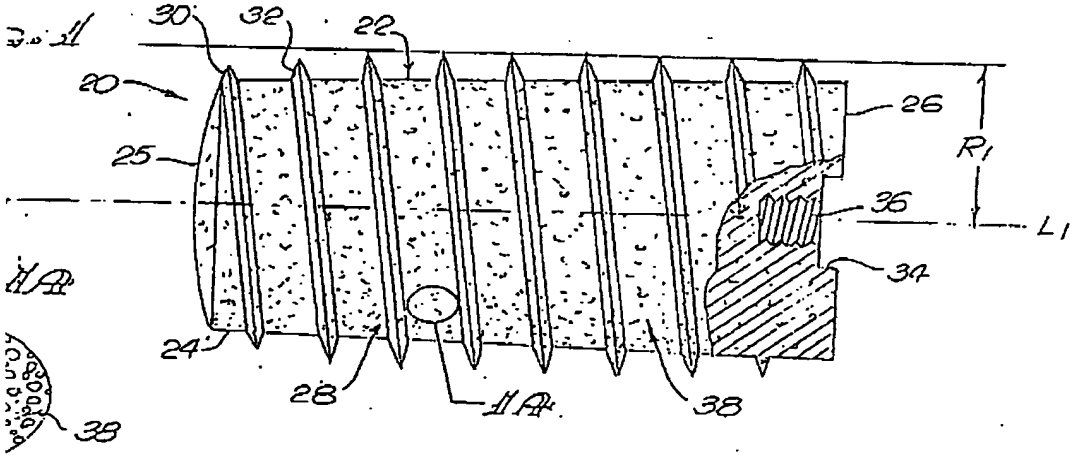


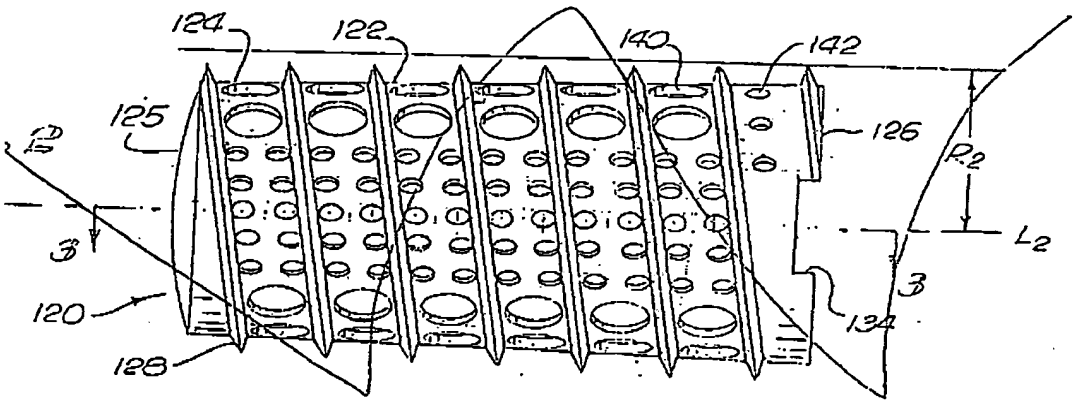


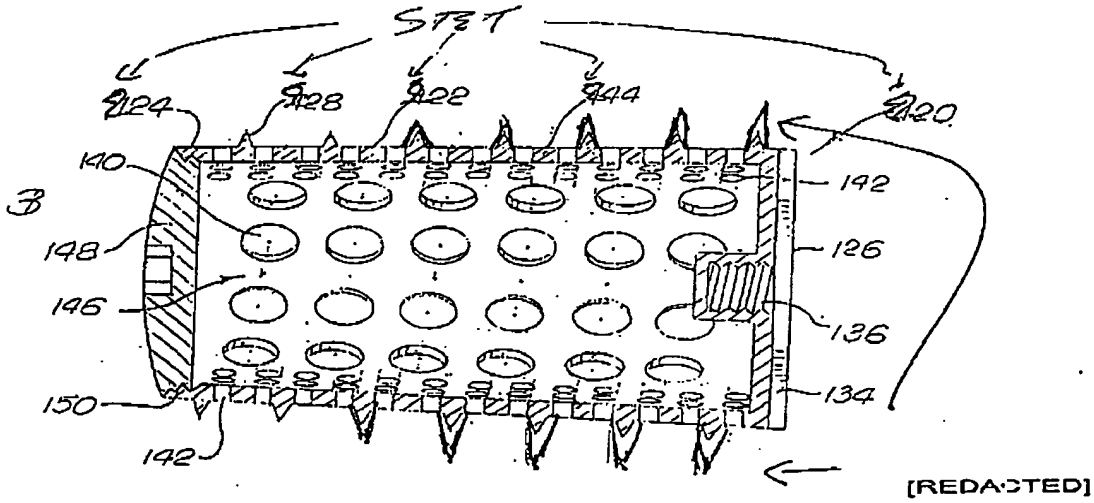


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FIG. 2

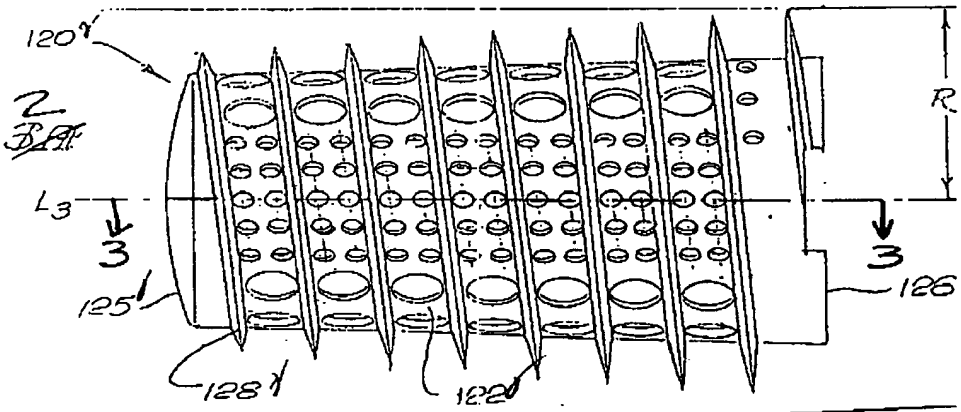


FIG. 4

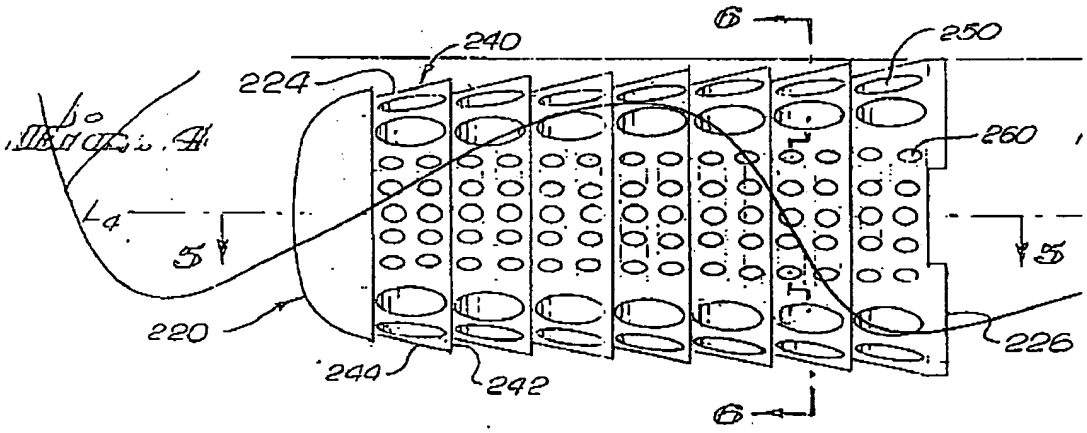


FIG. 5

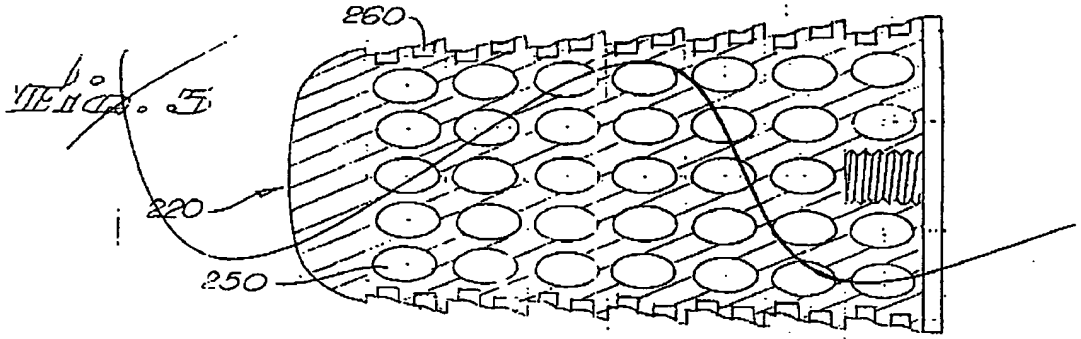


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FIG. 6

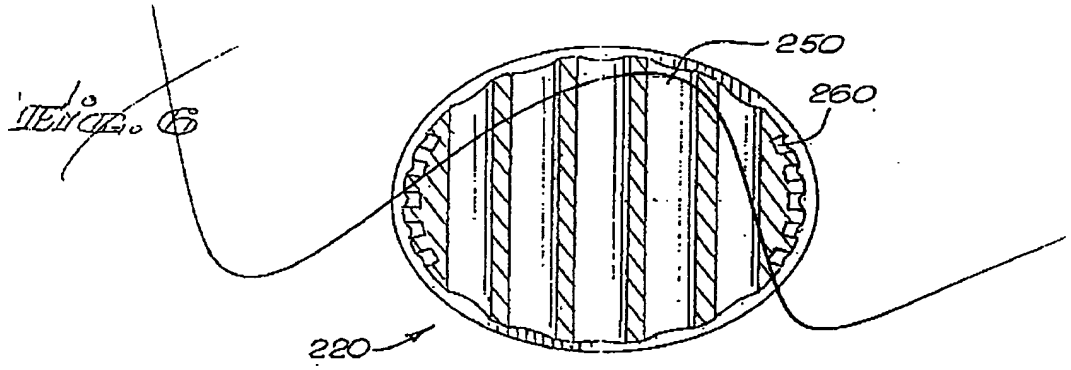



FIG. 6A

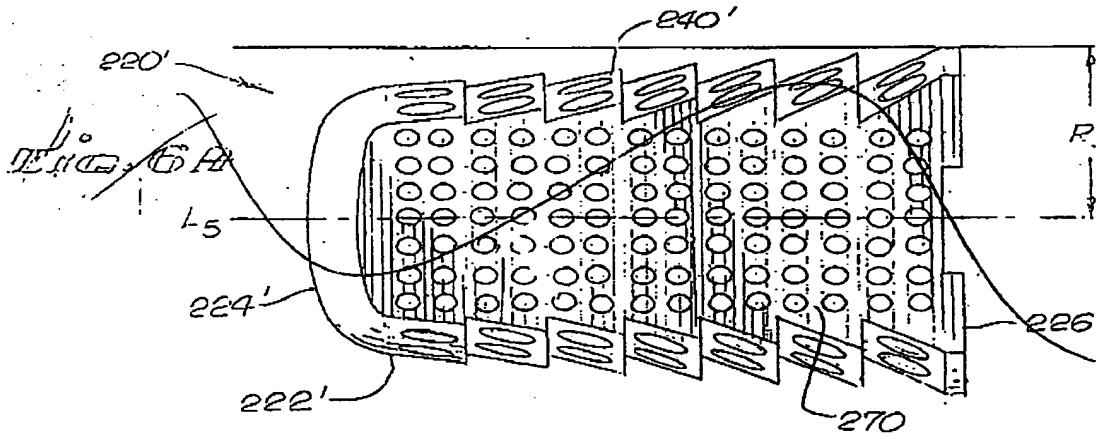
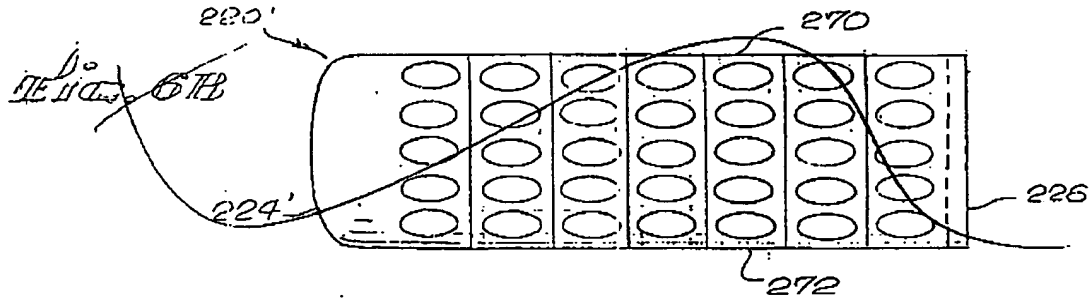



FIG. 6B



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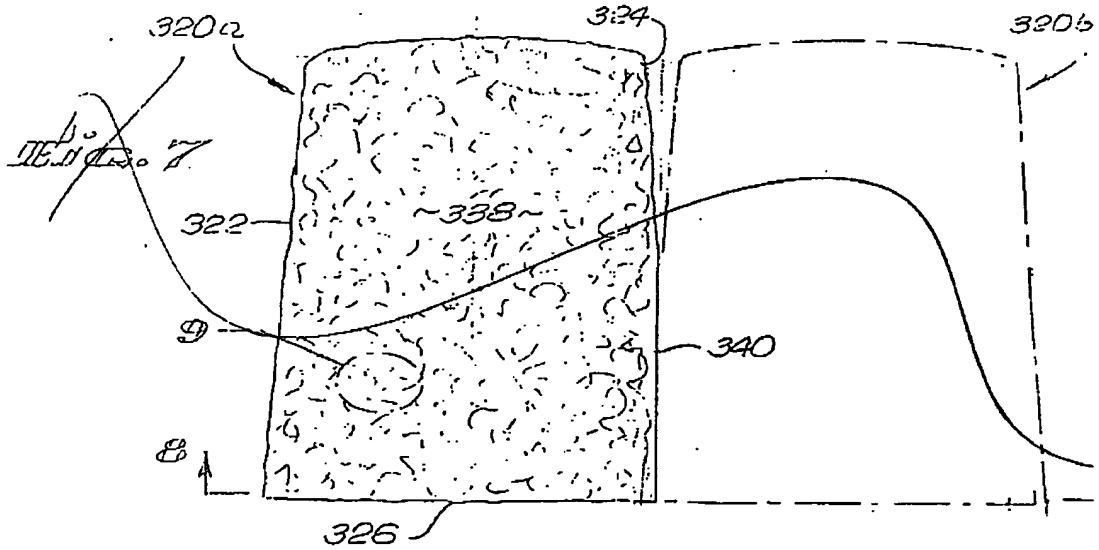


FIG. 7

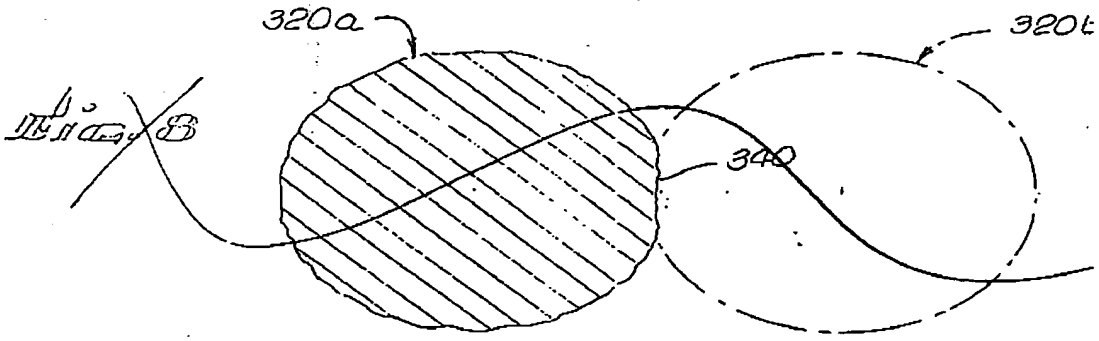


FIG. 8

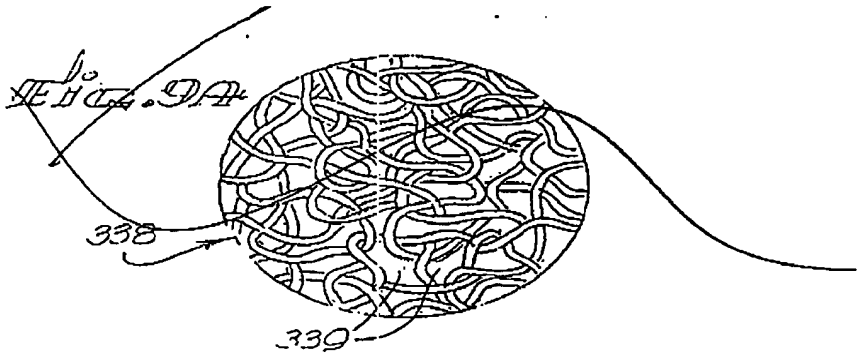


FIG. 9A

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FIG. 9B

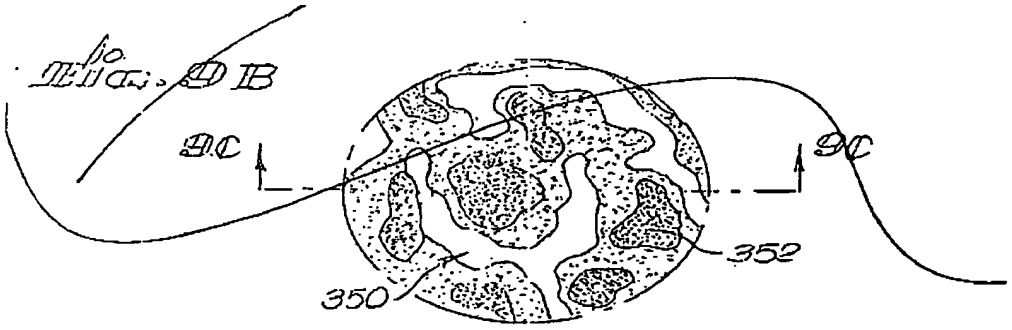


FIG. 9C

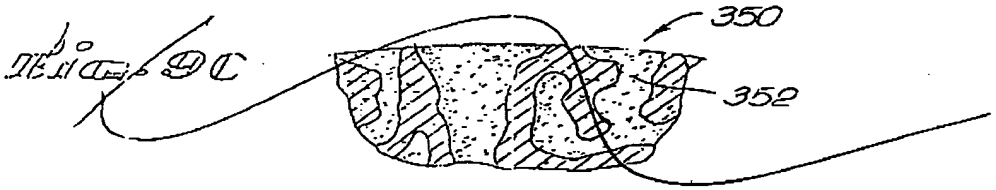


FIG. 10

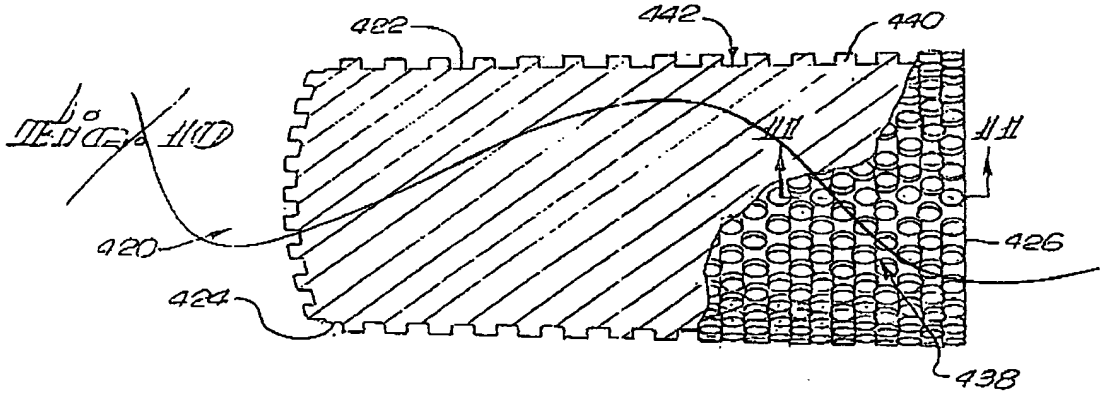


FIG. 11

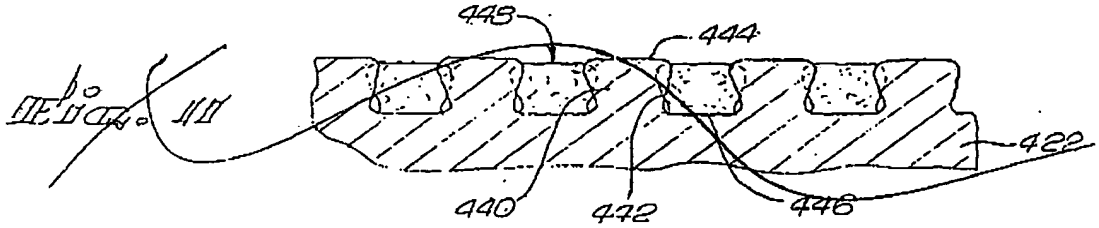


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FIG. 4B

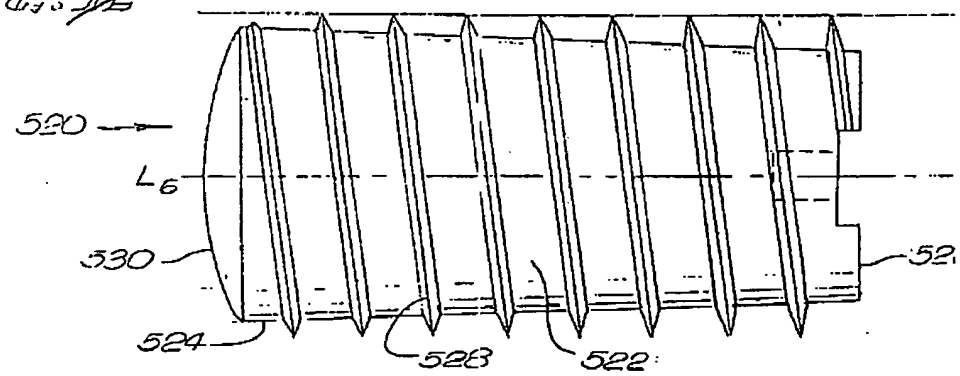


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FIG. 5B

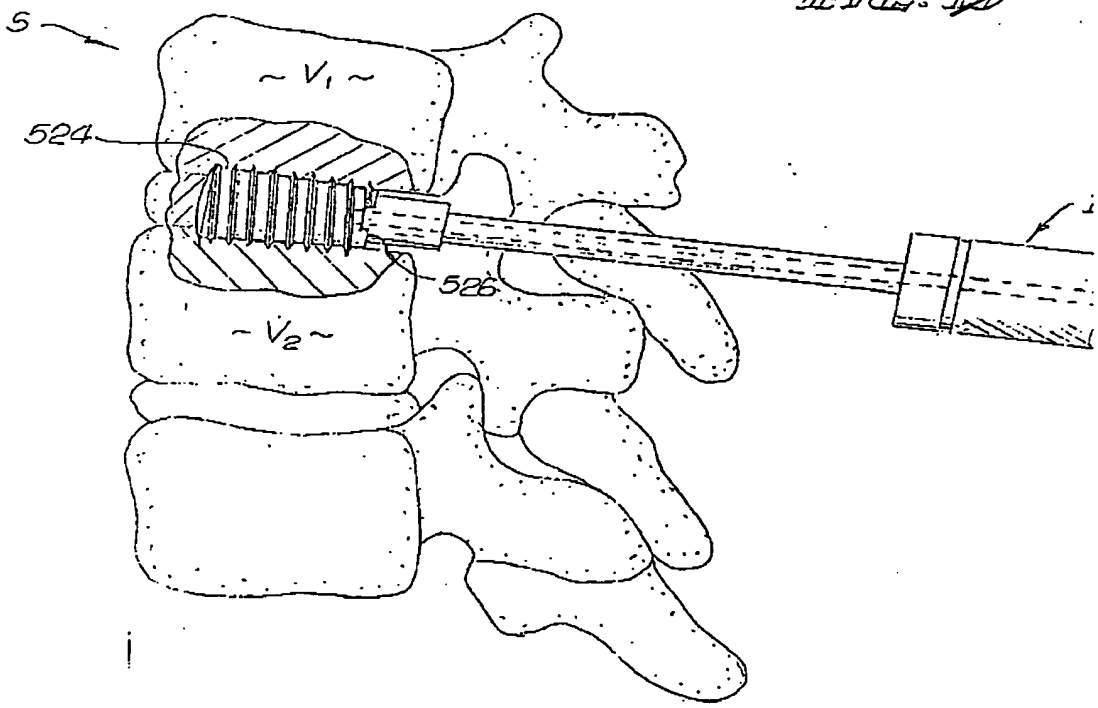


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FIG. 6

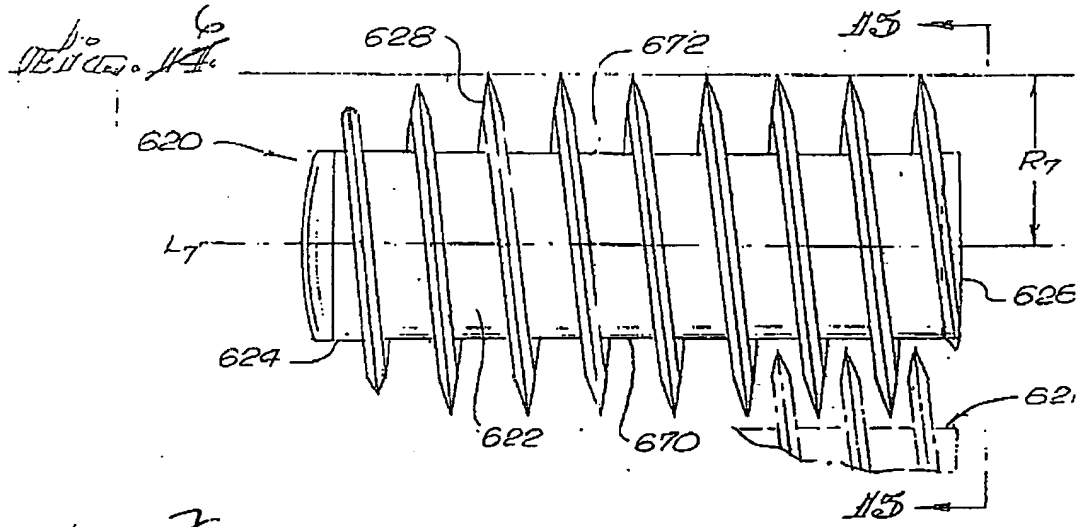


FIG. 7

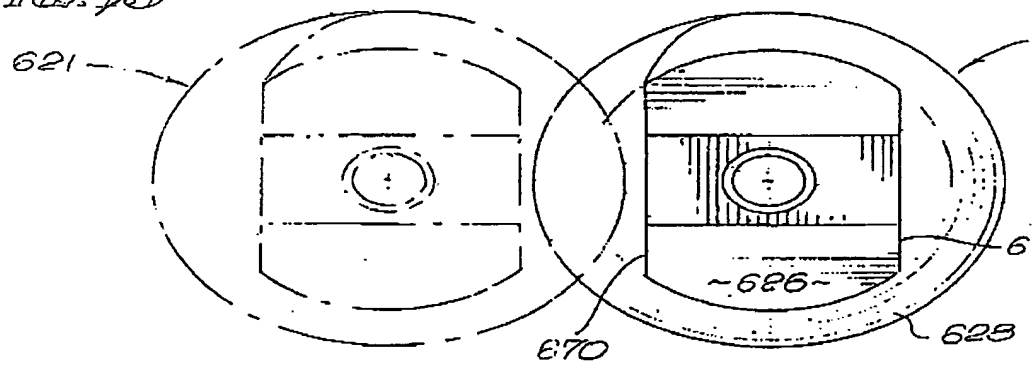


FIG. 8

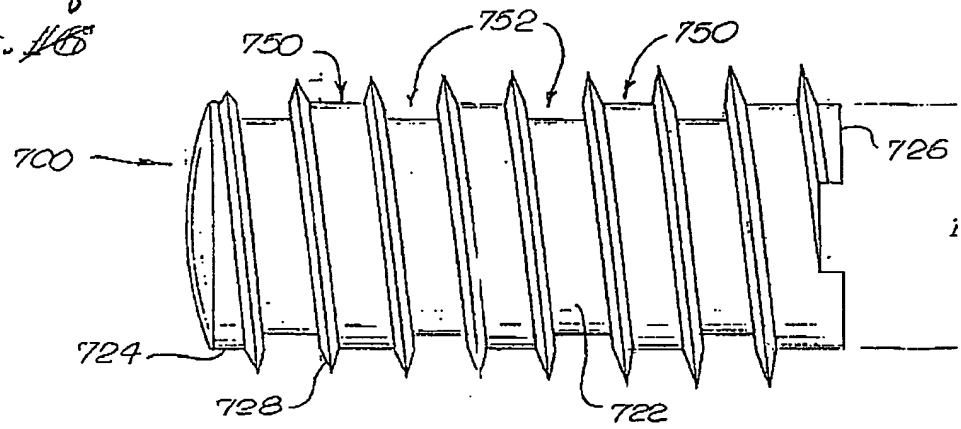


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FIG. 17

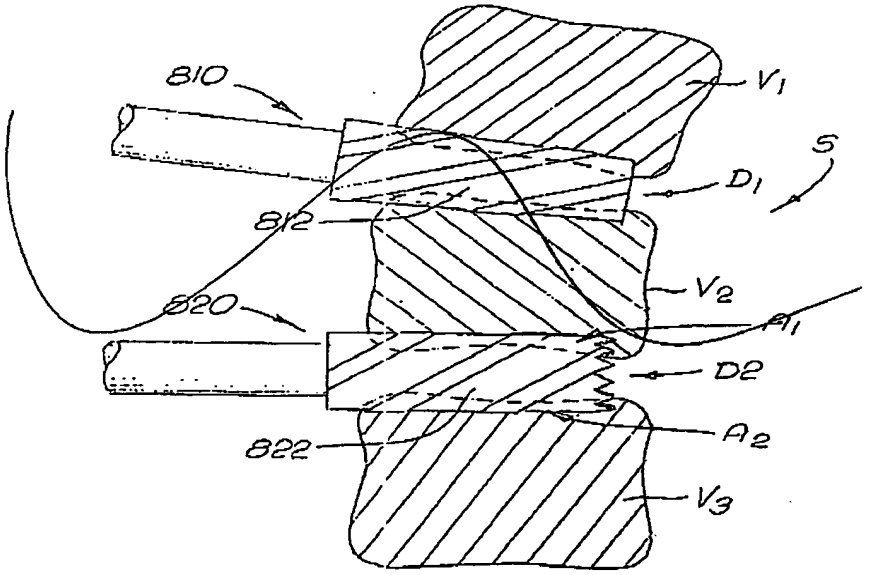



FIG. 18

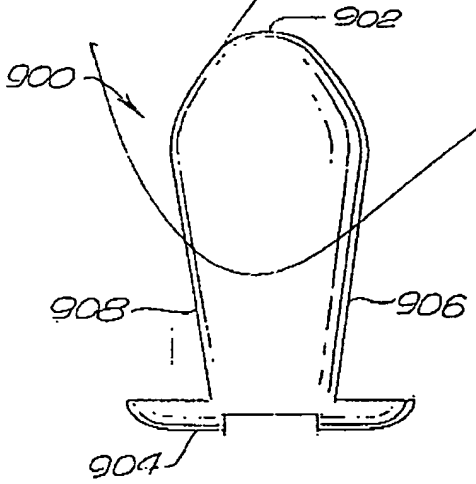
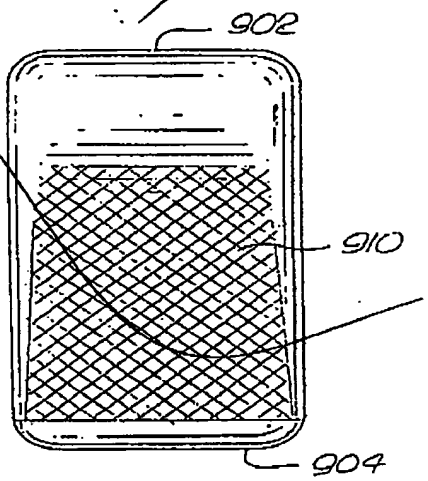



FIG. 19

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